

# United States Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/893,604	06/29/2001	Robert A. Hallowitz	BIOT1-11	6514
7590 01/25/2005			EXAMINER	
Theranostech, Inc.			PARKIN, JEFFREY S	
Attn: Patent Counsel 5741 Midway Park Blvd. NE			ART UNIT	PAPER NUMBER
Albuquerque, NM 87109			1648	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE @3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.136(s) in no event, however, may a reply be timely filed after SIX (s) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the manure statutory period within the statutory minimum of thirty (30) days will be considered timely.  If NO period for reply is specified above, the manure statutory period will apply and will explore IX (s) MONTHS from the mailing date of this communication.  Failure to reply within the set or extended period for reply will by statute, cause the application to become ABANDONED (35 U.S. C. § 133) Any reply resulted by the set or extended period for reply in specified above, the manure statutory period application to become ABANDONED (35 U.S. C. § 133) Any reply resulted from adjustment. See 37 CFR 1.704(s).  Status  1) Responsive to communication(s) filed on 29 October 2004  2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-17 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are allowed.  6) Claim(s) is/are allowed.  6) Claim(s) is/are allowed.  7) Claim(s) is/are allowed.  8) Claim(s) is/are allowed.  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note t		Application No.	Applicant(s)					
Juffrey S. Parkin, Ph.D. 1048  Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  If the parcial for reply specified above is less than thirty (30) days, at ley be timely fitted selected for reply specified above is less than thirty (30) days, at ley be considered the selected for reply specified above is less than thirty (30) days, at ley be considered the selected for reply specified above is less than thirty (30) days, at ley be considered the selected for reply specified above is less than thirty (30) days, at ley be considered the selected for reply specified above is less than thirty (30) days, at ley be considered from the selected for reply specified above is less than thirty (30) days, at less days (30) days, will be considered from the selected from	Office Action Commons	09/893,604	HALLOWITZ ET AL.					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE @ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provision of 3° CFR 1.13(d). In no event, however, may a reply be timely filled by the period for reply specified above is loss than fiving (30) days, a reply white the stationy minimum of bring (30) days, a reply white the stationy minimum of bring (30) days, a reply white the stationy minimum of bring (30) days, a reply white the stationy minimum of bring (30) days, a reply white the stationy minimum of bring (30) days, a reply white the stationy minimum of bring (30) days, and all grows (30) days, and all grows (30) days will all goods of this communication.  Faive to reply white the set of extended priori for reply will, by advantage days and elegans (30) days (30)	Office Action Summary	Examiner	Art Unit					
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THE MAILING DATE OF THIS COMMUNICATION.  Estensions of time may be available under the provision of 37 CFR 1.13(6). In no event, however, may a righty be timely filed after SIX (6) MONTHS from the mailing date of this communication. It is provided to the system of the six that the system of the six that the system of the system of the system of the six that the system of the sy	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
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#### Detailed Office Action

### Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 29 October, 2004, wherein claims 1, 8, and 11 were amended and new claim 17 submitted. Claims 1-17 are currently under examination.

## 35 U.S.C. § 112, Second Paragraph

Claims 1-16 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Concerning claim 1, the method has been amended to include an additional step (b). However, the inclusion of this step is confusing. Step (a) involves independent measurements involving two samples whereas step (b) appears to recombine the two samples to arrive at an "infectivity status". This additional step is confusing. Applicants are directed toward the bridging paragraph of pages 1 and 2 in the specification for further guidance. Step (a) involves the independent measurement of two paramaters (gp120 cell-surface expression and CD4 cell-surface expression). The values from these two measurements are combined to form a ratio (e.g., the number of cells per unit volume expressing cell-surface gp120 (productively infected cells)/the number of cells per unit volume expressing CD4) that enables the skilled artisan to ascertain the "infectivity status" of the patient. Appropriate correction is required.

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Claim 8 has been amended to recite a methodology employing a first anti-gp120 antibody attached to a label and a second labeled antibody specific for the first label. This recitation is confusing. Generally, an immunoassay might employ a first antibody (i.e., anti-gp120) and a second labeled antibody (i.e., anti-Ig[label]) that recognizes the first antibody. Alternatively, an immunoassay might employ two labeled antibodies with different specificities (i.e., anti-gp120[FITC] and anti-gp41[rhodamine]). Appropriate correction is required.

Claim 11 suffers from the same limitations as claim 1. The assessment step is confusing. The "infectivity status" of the host is assessed by combining the two fractions. Applicants are directed toward the bridging paragraph of pages 1 and 2 in the specification for further guidance. Step (a) involves the independent measurement of two paramaters (gp120 cell-surface expression and CD4 cell-surface expression). The values from these two measurements are combined to form a ratio (e.g., the number of cells per unit volume expressing cell-surface gp120 (productively infected cells)/the number of cells per unit volume expressing CD4) that enables the skilled artisan to ascertain the "infectivity status" of the patient. Appropriate correction is required.

### 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. § 102(b) as being anticpated by Zolla-Pazner et al. (1995). Applicants are reminded

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that the claims simply specify a method for measuring the number of cells expressing cell-surface gp120 and the number of cells expressing cell-surface CD4. Zolla-Pazner and colleagues describe a FACScan methodology to detect both cells expressing cell-surface gp120 and cell-surface CD4 from a sample. The assay employed a first labeled anti-gp120 antibody (anti-gp120[PE]) and second labeled anti-CD4 antibody (anti-CD4[FITC]). The results of the assay were reported in Figure 2. Thus, this teaching meets all of the claimed limitations.

### Finality of Office Action

Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE SHORTENED STATUTORY THEN THE SHORTENED THREE-MONTH PERIOD, STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

### Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center

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1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.

Primary Examiner
Art Unit 1648

22 January, 2005